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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,459	10/16/2003	Frank Clarke	P1519 US	3011

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MEDTRONIC VASCULAR, INC.  
IP LEGAL DEPARTMENT  
3576 UNOCAL PLACE  
SANTA ROSA, CA 95403

EXAMINER

FOSTER, JIMMY G

ART UNIT	PAPER NUMBER
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3728

DATE MAILED: 10/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/688,459

Applicant(s)

CLARKE ET AL.

Examiner

Jimmy G Foster

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 20 January 2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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1) Applicant's election without traverse of claims 1-8 is acknowledged. Accordingly, claim 9 is withdrawn from further consideration.

2) Claims 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 5, there is no antecedent basis for "the lid" introduced in line 2, making it unclear whether the lid is intended to be interpreted as present structure.

In claim 6, there is no antecedent basis for "the lid" introduced therein, making it unclear whether the lid is intended to be interpreted as present structure. Claim 7 depends from claim 6.

3) The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4) Claims 1, 2 and 4-7 are rejected under 35 U.S.C. § 102(b) as being anticipated by Morris et al (5,848,691). In the reference of Morris et al, there is provided a tray at 18, including channels at grooves 22,24, a recess at 32, and a recess at the angled portion 54. The tray is received in an outer pouch/wrapper defined by sheets 40,42.

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Although the reference of Morris et al does not disclose a coiled stent delivery system including a drug-coated stent as being the content of the tray 18, the channels 22,24 of Morris et al are inherently capable of receiving a coiled stent delivery system with drug coated stent which would have a size to be received in said channels. Inasmuch as Applicant's claims do not set forth the coiled stent delivery system and drug-coated stent as structure disposed in the tray, but as intended use, the capability of the channels 22,24 of Morris et al to receive an appropriately sized coiled stent delivery system with drug-coated stent therein meets what Applicant has claimed in this regard. Applicant is directed to MPEP 2114 regarding the treatment of intended use/functional limitations in a claim.

Similarly, although the reference of Morris et al does not disclose oxygen or moisture scavenger packs in the tray 18, the recesses 32,54 of Morris et al are inherently capable of receiving a scavenger packs having a small enough size to be received in said recesses. Inasmuch as Applicant's claims do not set forth the oxygen or moisture scavenger packs as structure disposed in the recesses in the tray, but as intended use, the capability of the recesses 32,54 of Morris et al to receive appropriately sized scavenger packs therein meets what Applicant has claimed in this regard.

Inasmuch as the lid of claim 5 or claim 6 is introduced indefinitely, the interpretation as present structure is in doubt. Although the reference of Morris et al does not appear to disclose a tray lid capable of overlying and thereby retaining scavenger packs in both recesses 32,54, the tray of 18 would be capable of being provided with a lid which covers the tray, including the recesses 32,54 to thereby retain scavenger packs in said recesses. Likewise, with respect to the lid of claim 6, the tray of Morris et al is inherently capable of being provided with a lid configured to be

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snap fit to the tray, such as by resilient lid-edge detents which could snap around the edges of the tray 18. Likewise, with respect to the lid of claim 7 and the additional fact that there is no indication in the claim that the lugs claimed have anything to do with the snap fit set forth in claim 6, the recesses 32,54 and the rectangular recess near the peripheral margin of the tray 18 of Morris et al are inherently capable of receiving lugs of a lid which otherwise snap fits around the edges of the tray 18 in the manner as described above.

5) Claims 1-4 are rejected under 35 U.S.C. § 102(b) as being anticipated by Dutchik (5,590,778). In the reference of Dutchik, there is provided a tray at tray-like member 16. A recess is provided at a central recess portion 22, and channels are provided at the general spiral recess 18 which is exterior to the portion 22. The channels receive a coiled cardiac catheter. With respect to Applicant's claim 4, the spiral channels 18 may be considered to define instead a second recess (in addition to a first recess 22).

The tray is received in a pouch 50, which includes a flexible sheets 52,54 and micro-porous patch 56.

Although the reference of Dutchik does not disclose the cardiac catheter in tray 16 as being a coiled stent delivery system having a drug-coated stent, the channels 18 of Morris et al are inherently capable of receiving a coiled stent delivery system with drug coated stent which would have a size adapted to be received in said channels. Inasmuch as Applicant's claims do not set forth the coiled stent delivery system and drug-coated stent as structure disposed in the tray, but as intended use, the capability of the channels 18 of Morris et al to receive an appropriately sized coiled

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stent delivery system with drug-coated stent therein meets what Applicant has claimed in this regard.

Likewise, although the reference of Dutchik does not disclose oxygen or moisture scavenger packs in the tray 16, the recesses 22,18 of Dutchik are inherently capable of receiving a scavenger packs having a small enough size to be received in said recesses. Inasmuch as Applicant's claims do not set forth the oxygen or moisture scavenger packs as structure disposed in the recesses in the tray, but as intended use, the capability of the recesses 22,18 of Dutchik to receive appropriately sized scavenger packs therein meets what Applicant has claimed in this regard.

6) Claims 1 and 3-5 are rejected under 35 U.S.C. § 102(b) as being anticipated by Cerwin (4,519,501). In the reference of Cerwin, there is provided a tray 31,35 including recesses defined at 43,43 (when flap 35 is closed on holding means portion 31). The tray is provided in an outer container 61,63, which may be considered to define a pouch since the container is said to be overwrapped (see col. 4, lines 21-32). There is also provided a lid at element 41 for covering the tray 31,35 within the pouch, including apertures at 42,42 in the lid which overlie the recesses 43,43.

A desiccant may be provided in the package of Cerwin.

Although the reference of Cerwin does not disclose a coiled stent delivery system including a drug-coated stent as being the content of the tray, the recess of element 31 of Cerwin is inherently capable of receiving a coiled stent delivery system with drug coated stent which would have a size to be received in the recess. Inasmuch as Applicant's claims do not set forth the coiled stent delivery system and drug-coated stent as structure

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disposed in the tray, but as intended use, the capability of the recess of element 31 of Cerwin to receive an appropriately sized coiled stent delivery system with drug-coated stent therein meets what Applicant has claimed in this regard.

Likewise, although the reference of Cerwin does not disclose oxygen or moisture scavenger packs in the tray 31,35, the recesses 43,43 of Cerwin are inherently capable of receiving scavenger packs having a small enough size to be received in said recesses and below the lid 41. Inasmuch as Applicant's claims do not set forth the oxygen or moisture scavenger packs as structure disposed in the recesses in the tray, but as intended use, the capability of the recesses 43,43 of Cerwin to receive appropriately sized scavenger packs therein meets what Applicant has claimed in this regard.

7) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8) Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Morris et al (5,848,691) in view of Aday (4,406,363). Although the reference of Morrison does not disclose a pouch 40,42 being made of a plastics covered foil, the reference of Aday suggests that a conventional sterile envelope/pouch for a medical article may be made of aluminum foil coated with thermoplastic, for maintaining a hermetic enclosure and therefore sterile condition for the article (see col. 3, lines 64-68 and col. 6, lines

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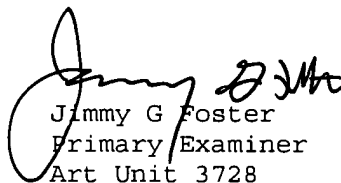
37-57). The container is sterilized and then sealed in the envelope.

Accordingly, it would have been obvious in view of this teaching to have made the pouch 40,42 of Morris et al of plastics covered aluminum foil.

9) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jimmy G Foster whose telephone number is (703) 308-1505. The examiner can normally be reached on Mon-Fri, 8:45 am - 5:15 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (703) 308-2672. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

  
Jimmy G Foster  
Primary Examiner  
Art Unit 3728

JGF  
26 October 2004